

Evaluation Report for Category B, Subcategory 2.1 (Change in guarantee), 2.3 (Identity of formulants), 2.4 (Proportion of formulants) Application

Application Number: 2005-1383
Application: Evaluation Report for Category B, Subcategory 2.1 (Change in guarantee), 2.3 (Identity of formulants), 2.4 (Proportion of formulants)
Product: Goal 2XL Herbicide Emulsifiable Concentrate
Registration Number: 24913
Active ingredients (a.i.): Oxyfluorfen
PMRA Document Number: 1364607

Background

Goal 2XL Herbicide (a restricted end-use product) contains oxyfluorfen as an active ingredient, and is currently registered in Canada under Use Site Category # 14 for the control of labelled broadleaf weeds in dry bulb onion, strawberry, and raspberry at the application rate of 248 g ai/ha. The use of Goal 2XL in Canada is restricted to licensed pest control operators and it is applied only by ground application.

Recently, oxyfluorfen has been re-evaluated in Canada (PACR 2005-03) and the US. The federal Toxic Substances Management Policy and Pest Management Regulatory Directive (DIR 99-03) were taken into consideration during the re-evaluation of oxyfluorfen, and it was concluded that oxyfluorfen is not a candidate for Track 1 classification (PACR 2005-03).

Purpose of Application

The purpose of this application was to change the guarantee and the identity and proportion of formulants of Goal 2XL EC. The amount of active ingredient is reduced from 248 to 240 g ai/L. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Goal 2XL Herbicide Emulsifiable Concentrate is formulated as an emulsifiable concentrate containing oxyfluorfen at a new nominal concentration of 240 g/L. This end-use product has a density of 1.077 g/mL and pH of 7.22. The product contains a petroleum distillate. The chemistry requirements for Goal 2XL Herbicide Emulsifiable Concentrate are complete.

Health Assessment

The changes in formulation are not expected to significantly alter the toxicology profile of Goal 2XL Herbicide. No toxicity data was submitted and none is required.

The proposed formulation and guarantee changes to Goal 2XL Herbicide should not result in an increase of exposure to oxyfluorfen for mixer/loader/applicators or for workers re-entering treated areas. Use patterns are identical to those registered, the only difference being a slight decrease in the active guarantee, which should result in marginally lower exposure.

To support the new formulation of Goal 2XL Emulsifiable Concentrate Herbicide (change in guarantee, identity and proportion of formulants), no new residue data were submitted. Following the comparison of the new formulation to the original formulation (PCP# 24913), there is no indication that the decrease in guarantee or change in any of the formulants will have an impact on the magnitude of the residues of oxyfluorfen, when the new formulation is used according to the label. Therefore, no increase in dietary exposure is anticipated. The change in the formulation will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limit(s)

Based on the maximum residues observed in crops treated according to label directions, residues of oxyfluorfen in strawberries are covered under the established MRL of 0.05 ppm. Residues of oxyfluorfen in red raspberries and dry bulb onions are covered under the 0.1 ppm General Regulations of the FDAR.

Environmental Assessment

The change in formulation was considered minor and is not expected to increase the environmental exposure of this product.

Value Assessment

As the substitution of one component such as a surfactant or emulsifier with a similar volume of a similar component has not been a major influence for herbicide product performance or crop tolerance from an historic perspective, value data in support of the alternative formulation for Goal 2XL Emulsifiable Concentrate are not required.

Conclusions

The Agency has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Goal 2XL EC Herbicide.

References

A. List of studies/information submitted by registrant:

Chemistry Assessment

PMRA 1079821. Determination of color, physical state, odor, oxidizing and reducing action, flammability, explodability, pH, viscosity and density of GF-1243, an end-use product containing oxyfluorfen. Dow AgroSciences LLC, Study No. FAPC033254. Study report date: 29-Sep-2003. 19 pp. DACO 3.5.

PMRA 1054376. Development and accelerated storage stability in glass of Goal 2XL formulation GF-1243. Dow AgroSciences LLC, Study No. NAFST 745. Study report date: 18-Sep-2003. 16 pp. DACO 3.5.10.

PMRA 1325236. Storage stability and package corrosion characteristics of GF-1243: One-year study. Dow AgroSciences LLC, Study ID FOR-05-033. Study report date: 06-Nov-2006. 23 pp. DACO 3.5.10 and 3.5.14.

PMRA 1085396. Group A: Product identity and composition, description of materials used to produce the product, description of the formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method for Goal 2XL Herbicide (GF-1243), an end use product. Dow AgroSciences LLC, Study No. NAFST-05-133. Study report date: 02-Oct-2005. 12 pp. DACO 3.2.

PMRA 1079820. Analytical method and validation for the determination of oxyfluorfen in Goal 2XL and Goal 40 WP. Dow AgroSciences LLC, Study ID DAS-AM-01-043. Study report date: 07-Jan-2002. 34 pp. DACO 3.4.1.

Value Assessment

PMRA 1079822. Value summaries. Dow AgroSciences. Study report date: 06-Oct-2005. pp. 1 DACO 10.2.3.1 and DACO 10.3.1.

B. Additional information considered

I) Published information

EAD Assessment

Proposed Acceptability for Continuing Registration (PACR 2005-03). Re-Evaluation of Oxyfluorfen, June 30, 2005. pp.9.

Toxic Substances Management Policy and Pest Management Regulatory (DIR 99-03). March 12, 1999. pp.10.

ii) Unpublished information

None.

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